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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/451,739	11/30/1999	DIRK JAGER	LUD-5615	9448

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EXAMINER
NICKOL, GARY B

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/451,739	JAGER ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-79 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-79 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-79 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 10-21, 27-28, and 78, drawn to isolated nucleic acids encoding specific cancer-associated antigens, vectors, transformed cells thereof, and immunogenic nucleic acids encoding such antigens, classified in class 536, subclass 23.5; class 435, subclass 325, 320.1; class 514, subclass 44.

II. Claims 9, 22-23, 26, 34 drawn to specific isolated cancer associated antigens and immunogenic compositions thereof, classified in class 530, subclass 350; class 514, subclass 2.

III. Claims 24-25,53-57 drawn to immunogenic proteins comprising at least one peptide consisting of an amino acid sequence of from 8 to 12 (or 8 to 25) amino acids long concatenated to each other and vectors thereof, classified in class 514, subclass 2; class 435, subclass 320.1.

IV. Claims 29-33, drawn to a vaccine comprising an isolated eukaryotic cell line and a pharmacologically acceptable adjuvant, classified in class 424, subclass 93.21.

V. Claims 35-36, drawn to isolated antibodies specific for the cancer associated antigens, classified in class 530, subclass 387.7.

VI. Claims 37, and 62-65, drawn to methods of screening for pathological conditions comprising contacting a sample with a nucleic acid molecule which hybridizes to all or part of the molecule encoded by SEQ ID Nos: 1-4, 8 or 15, classified in class 435, subclass 6; class 436, subclass 64.

VII. Claim 38, drawn to a method of screening for cancer in a sample comprising contacting said sample with an antibody to a target as an indicator of cancer, classified in class 435, subclass 7.23.

VIII. Claims 39, 52, 77 drawn to a method for diagnosing a cancerous condition comprising contacting an immunoreactive cell from a subject to a cell line transfected with cancer associated genes and determining the interaction of the two cell types as an indicator of cancer, classified in class 435, subclasses 4, 29-30.

IX. Claims 40 and 66 (in part), and claims 41-45,50, 67-71,75 as specifically drawn to a method for monitoring the progression or regression of cancer in a patient by specifically monitoring a protein (or derivative thereof) encoded by SEQ ID Nos: 1-4, 8 or 15, classified in class 424, subclass 9.1; class 436, subclass 64.

X. Claims 40 and 66 (in part), and claims 46-49, 67-68,72-74 as specifically drawn to a method for monitoring the progression or regression of cancer in a patient by specifically monitoring RNA encoding a cancer associated antigen, classified in class 424, subclass 9.1; class 436, subclass 6.

XI. Claims 40 and 66 (in part), and claims 42, 68 as specifically drawn to a method for monitoring the progression or regression of cancer in a patient by specifically monitoring cytolytic T-cells specific for a cancer associated antigen and an MHC molecule with which it non-covalently complexes, classified in class 424, subclass 9.1.

XII. Claims 40 and 66 (in part), and claims 41-42, 51, 58-61, 67-68, 76 as specifically drawn to a method for monitoring the progression or regression of cancer in a patient by specifically monitoring antibodies specific for a CT protein, classified in class 424, subclass 9.1; class 436, subclass 64.

XIII. Claim 79, drawn to isolated nucleic acid molecule, the complimentary sequence of which hybridizes under stringent conditions to the nucleotide set forth in SEQ ID Nos: 4, 5, 8 or 15, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

The Inventions of Groups I-V, XIII represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects.

The inventions of Groups VI-XII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The invention of Group I and the methods of Groups VI and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the nucleic acid product as claimed can be used in a materially different process such as affinity chromatography.

The invention of Group II and the method of Group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the protein product as claimed can be used in a materially different process such as methods of immunizing a host.

The invention of Group V and the methods of Groups VII, IX, and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography.

The invention of Groups II, V and XIII and the methods of Groups VI-XII are not at all related because the products of Groups II, V and XIII are not used in any of said methods.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
February 12, 2003